EXHIBIT A

RUN DATE: 12/30/2014 Bexar County Centralized Docket System Pg: 1 PGM: DKB4900P
RUN TIME: 13:02:28 JCL: SPPROD

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* D O C K E T I N F O R M A T I O N *

CAUSE NUM: 2014CI19749
DATE FILED: 12/22/2014 COURT: 037 UNPAID BALANCE: 0.00
TYPE OF DOCKET: OTHER CIVIL CASES

* * * S T Y L E * * *

XENEX DISINFECTION SERVICES LLC
VS SPECTRA254 LLC

ACCOUNT TYPE: ACCOUNT NO:
ACCESS: 0 STATUS: PENDING
LIST TYPE: C

* L I T I G A N T I N F O R M A T I O N *

SEQ	LAST /FIRST /MIDDLE NAME	LIT. TYPE/ATTORNEY	DATE
00001	XENEX DISINFECTION SERVICES LLC	PLAINTIFF	12/22/2014
		00001 SCRAFFORD, J BRUCE	
00002	SPECTRA 254 LLC	DEFENDANT	12/22/2014

* S E R V I C E S I N F O R M A T I O N *

SEQ	SERVICE TYPE / DATES	DIST	LITIGANT NAME

* A T T O R N E Y I N F O R M A T I O N *

SEQ	DATE FILED	BAR NBR.	NAME	STATUS	DATE
00001	12/22/2014	17931100	SCRAFFORD, J BRUCE	SELECTED	12/22/2014

* P R O C E E D I N G I N F O R M A T I O N *

SEQ	DATE FILED	REEL	IMAGE	PAGE COUNT
00001	12/22/2014	0000	0000	0000
	DESC: PETITION			
00003	12/22/2014	0000	0000	0000
	DESC: SERVICE ASSIGNED TO CLERK 3			

* T R I A L I N F O R M A T I O N *

SEQ	DATE FILED	COURT	SETT. DATE	TIME	ATTY
00002	12/22/2014	109	01/05/2015	09:00AM	
	DESC: NON-JURY TRIAL				
	SETTING ON TEMPORARY INJUNCTION				

* O R D E R I N F O R M A T I O N *

SEQ	DATE FILED	JUDGE NAME	VOLUME	PAGE	PAGE CNT	AMOUNT	SOF
00001	12/22/2014	DAVID A. CANALES	4322	2170	0002	0.00	
	DESC: TEMP RESTRAINING ORDER						
	AND ORDER SETTING HEARING FOR						
	PRELIMINARY INJUNCTION						

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* B O N D I N F O R M A T I O N *

SEQ	DATE FILED	PRINCIPAL
00001	12/22/2014	XENEX DISINFECTION SERVIC

AGENT: AMOUNT: 500.00

SURETY: CASH DEPOSIT IN LIEU OF

REASON: TEMP REST ORDER FORM: CASH

CAUSE NO. 2014-CI-19749

XENEX DISINFECTION SERVICES LLC, *Plaintiff*	§	**IN THE DISTRICT COURT**
	§	37th **JUDICIAL DISTRICT**
v.	§	
SPECTRA254, LLC, *Defendant.*	§	**BEXAR COUNTY, TEXAS**

TEMPORARY RESTRAINING ORDER AND ORDER SETTING HEARING FOR PRELIMINARY INJUNCTION

On the 22nd day of December, 2014, the court heard Plaintiff's application for temporary restraining order.

1. The court, after examining the pleadings and affidavits, finds:

   a. Plaintiff will probably prevail against Defendant;

   b. Harm is imminent and irreparable to Plaintiff because Plaintiff and Defendant are competitors and Defendant is making false and misleading statements about the safety of Plaintiff's product in order to promote Defendant's product. Under these circumstances, harm is presumed pursuant to the Lanham Act.

   c. There is an inadequate remedy at law in the event an injunction is not issued because damages caused by false and misleading statements disparaging the reputation of a company and its product are difficult to quantify and not readily compensated by an award of money damages; and

   d. An ex parte order is necessary without notice to Defendant because Defendant has already made false and misleading statements about Plaintiff's product,

there is insufficient time to give notice to Defendant, hold a hearing, and issue a restraining order before additional harm occurs.

It is therefore ORDERED, ADJUDGED and DECREED as follows:

a. Defendant is enjoined to immediately cease publishing false and misleading statements about Plaintiff and its product, and in particular shall refrain from making additional statements to the effect that the Xenex Disinfection Device is unsafe because 1) the device was never tested for Safety UL 61010-1, 2) Xenex does not publish test data to demonstrate its device's effectiveness in killing pathogens and/or 3) Xenex never tested against Ebola; and

b. The clerk is ordered to issue notice to Defendant that the hearing on Plaintiff's application for temporary injunction is set for January 5, ~~2014~~ 2015, at 9:00 a.m./~~p.m.~~ in Presiding District Court, Bexar County Courthouse, 100 Dolorosa, Room 1.09, San Antonio, Texas 78205.

c. Bond is set for the issuance of the temporary restraining order in the amount of $ 500.00.

This Order shall remain in effect for 14 days from the date of signature unless extended pursuant to TEX. R. CIV. P. 680.

This Order is binding upon the parties to this action, their officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise.

SIGNED this the 22nd day of December, 2014, at 1:50 ~~a.m.~~/p.m.

PRESIDING JUDGE

{W0643858.1}

2014CI19749 -B00001

**Certificate of District Clerk That Plaintiff(s)
Made Cash Deposit In Lieu Of
Temporary Restraining Order Bond**

CRT

**The State of Texas
County of Bexar**

37th Judicial District Court

I, Donna Kay McKinney, Clerk of the District Courts in and for Bexar County, Texas, do hereby certify that XENEX DISINFECTION SERVICES, L.L.C., in Cause No. 2014CI19749, Styled XENEX DISINFECTION SERVICES, L.L.C., vs. SPECTRA254, L.L.C., have this day deposited the sum of FIVE HUNDRED DOLLARS ($500.00) cash, which is the amount ordered by the Court in lieu of a Temporary Restraining Order Bond.

WITNESS, Donna Kay McKinney, Clerk of the District Courts of Bexar County, Texas. Given under my hand and seal of said Courts of Bexar County, Texas, on December 22, 2014.

**Donna Kay McKinney
District Clerk, Bexar County, Texas**

BY: _____
Paul Dulia, Deputy

*** * RECEIPT REQUIRED FOR REFUND OF FUNDS**

FILED
DONNA KAY McKINNEY
DISTRICT CLERK
BEXAR COUNTY

14 DEC 22 PM 2:22

DEPUTY

BY _____

DOCUMENT SCANNED AS FILED

CIT PPS - SAC3

CAUSE NO. 2014CI19749

XENEX DISINFECTION SERVICES LLC, *Plaintiff*	§	**IN THE DISTRICT COURT**
v.	§	**37TH JUDICIAL DISTRICT**
SPECTRA254, LLC, *Defendant.*	§	**BEXAR COUNTY, TEXAS**

PLAINTIFF'S ORIGINAL PETITION AND APPLICATION FOR TEMPORARY RESTRAINING ORDER AND TEMPORARY INJUNCTION

Plaintiff XENEX DISINFECTION SERVICES LLC, for cause of action against Defendant SPECTRA254, LLC alleges as follows:

I.
DISCOVERY CONTROL PLAN

1. Pursuant to Rule 190.1 of the Texas Rules of Civil Procedure, Plaintiff intends to conduct discovery in this case under Level 2.

II.
PARTIES

2. Plaintiff XENEX DISINFECTION SERVICES LLC ("Xenex") is a Texas limited liability company.

3. Defendant SPECTRA254, LLC is a foreign limited liability company with a principal business address of 3 Corporate Drive, Unit C, Danbury, Connecticut 06810, that may be served via its registered agent for service of process, United Corporate Services, Inc., 66 Cedar Street, Newington, Connecticut 06111.

III.
JURISDICTION AND VENUE

4. This Court has personal jurisdiction over Defendant, and the amount in controversy in this matter exceeds the minimum jurisdictional limits of this Court. Defendant is authorized to conduct business in Texas and markets its product for sale in Texas

5. Venue is proper in Bexar County pursuant to §15.002(1) and/or 15.002(4) of the Texas Civil Practice and Remedies Code because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in Bexar County and/or Plaintiff resided in Bexar County at the time its cause of action accrued, and Defendant does not reside in Texas or maintain a principal office in Texas.

IV.
FACTS IN SUPPORT OF ALL CLAIMS

6. Xenex is engaged in interstate commerce in the production and sale of proprietary ultraviolet hospital disinfection equipment. Defendant is a competitor engaged in interstate commerce in the sale of hospital disinfection equipment.

7. Defendant has engaged in a pattern of unfair business practices and unfair competition against Xenex, which most recently included Defendant making false or misleading descriptions of fact and/or false or misleading representations of fact in connection with the commercial advertising or promotion of its goods, which misrepresented the nature, characteristics or qualities of Xenex's product, services or commercial activities.

8. Defendant has circulated an email that 1) directs potential customers to a website promoting its own product and 2) makes the following false and/or misleading representations of fact about Xenex's product:

A. "XENEX Pulsed UV system never tested for Safety UL 61010-1"

B. "Xenex never publishes real independent test data to demonstrate its effectiveness in killing pathogens. WHY NOT???"

C. "Xenex never tested against Ebola"

9. Attached as Exhibit 1 is a true and correct copy of an email (save and except for the redaction of the recipient's e-mail address) in which Defendant makes the above-described false and/or misleading representations about Xenex's product.

10. Defendant's representation that: "Xenex Pulsed UV system never tested for Safety UL 61010-1", is false and/or misleading because the Xenex device has been tested by Intertek Testing Services for compliance with UL 61010-1. Attached as Exhibits 2 and 3 are true and correct copies of Intertek documents confirming that the Xenex UV Disinfection Device has been tested for and found to comply with UL 61010-1.

11. Defendant's representation that: "Xenex never publishes real independent test data to demonstrate its effectiveness is killing pathogens" is false and/or misleading because the Xenex device has been the subject of several published and peer reviewed studies that indicate the device is effective in killing pathogens. Such studies are referenced and made available on Xenex's website. True and correct copies of examples of such published studies are attached as Exhibits 4, 5 and 6.

12. Defendant's representation that "Xenex never tested against Ebola" is misleading because the industry standard for testing the effectiveness of a disinfection method or device in killing the Ebola virus is to test the method or device on an Ebola surrogate rather than the actual Ebola virus. For obvious reasons, no responsible manufacturer tests against the actual Ebola virus. Defendant represents on its own website that its own device "quickly destroys the Ebola virus...."; however, the study referenced on the same website to verify such claim notes that the

device was tested on an Ebola surrogate. The Xenex device has also been tested on and found effective in killing a recognized Ebola surrogate.

V.

APPLICATION FOR TEMPORARY RESTRAINING ORDER AND TEMPORARY INJUNCTION

13. Plaintiff re-alleges and incorporates herein by reference its allegations in paragraphs 1-12 above.

14. Plaintiff is entitled to, and requests, a Temporary Restraining Order and Temporary Injunction that restrains Defendant from making additional false and/or misleading representations about Xenex's Disinfection Device, including but not limited to representations that state or imply that the Device is unsafe because it fails to comply with ULK 61010-1, is untested in killing pathogens or untested against Ebola. Plaintiff requests that the Temporary Restraining Order restrain such activities for a period of not more than 14 days. Following notice and a hearing, Plaintiff requests that a Temporary Injunction be issued to restrain such activities until such time as the Court rules on Plaintiff's application for permanent injunction.

15. Defendant's conduct as described above constitutes an actionable violation of the Lanham Act pursuant to 15 U.S.C.A. §§ 1125(a)(1). Plaintiff is entitled to injunctive relief pursuant to 15 U.S.C.A. §1116 to restrain Defendant from such unlawful conduct.

16. Because Plaintiff and defendant are competitors, harm is presumed from Defendant's false representations about Plaintiff's product, and no evidence of actual injury is required to support an application for temporary injunction under the Lanham Act. *See* e.g. McNeilab, Inc. v. American Home Products Corp., 848 F 2d 34, 38 (2nd Cir. 1988).

17. Plaintiff is willing to post a reasonable bond, and requests that the court fix a reasonable bond for the Temporary Restraining Order. Plaintiff further requests that the court set

Plaintiff's Application for Temporary Injunction for hearing. Following the Temporary Injunction hearing, Plaintiff requests that the court fix a reasonable bond for the Temporary Injunction and set this matter for trial. Plaintiff is willing to post a reasonable bond for the Temporary Injunction.

18. Attached hereto as Exhibits 7 and 8 and incorporated herein by reference, are affidavits verifying the facts supporting this Application for Temporary Restraining Order and Temporary Injunction. There is insufficient time to wait for the scheduling of a Temporary Injunction hearing before enjoining Defendant's conduct because Defendant's actions are likely to cause Plaintiff additional harm prior to the time of such Temporary Injunction hearing.

19. It is probable that Plaintiff will prevail on the merits because the actions described above constitute actionable violations of the Lanham Act.

20. If an injunction does not issue, Plaintiff will suffer irreparable injury for which not adequate remedy exists, and the continued dissemination of false, misleading and damaging representations about the safety of Plaintiff's Device creates a probable, imminent, and irreparable injury that qualifies for injunction relief. Finally, Plaintiff asserts that injunctive relief is the proper remedy to maintain the status quo, pending a resolution of the case.

21. This requested relief is authorized pursuant to Section 65.011(1), (2), (3), and/or (5) of the Texas Civil Practice and Remedies Code and/or 15 U.S.C.A. § 1116.

VI.
APPLICATION FOR PERMANENT INJUNCTION

22. Plaintiff re-alleges and incorporates by reference paragraphs 1 – 21 above.

23. Pursuant to 15 U.S.C.A. § 1116 Plaintiff request and is entitled to a permanent injunction restraining the same conduct that is the subject of Plaintiff's application for temporary

injunction, and further requiring Defendant to advertise and/or send out retraction e-mails in order to correct its prior misrepresentations, and further requiring Defendant to file a verified report setting forth in detail the manner in which it has complied with the injunction, as provided by 15 U.S. C.A. § 116(a).

VII.

CLAIM FOR RECOVERY OF DEFENDANDANT'S ILLEGAL PROFITS AND STATUTORY AWARD

24. Plaintiff re-alleges and incorporates by reference paragraphs 1 – 23 above.

25. Pursuant to 15 U.S.C.A. § 1117, Plaintiff requests and is entitled to recover 1) any profits made by Defendant that resulted from its violation of the Lanham Act; 2) treble amounts authorized by 15 U.S.C.A. § 1117 and/or 3) an additional award damages authorized by 15 U.S.C.A. § 1117 in the event the Court determines that treble damages are inadequate according to the circumstances of the case.

VIII.

CLAIM FOR ATTORNEYS FEES

26. Plaintiff re-alleges and incorporates by reference paragraphs 1 – 25 above.

27. Plaintiff requests and is entitled to an award for costs and attorney's fees against Defendant because Defendant's misrepresentations and misleading statements were intentional or reckless and this constitutes an exceptional case pursuant to 15 U.S.C.A. § 1117.

IX.
PRAYER

Plaintiff asks that Defendant be cited to appear, and that the Court enter a judgment against Defendant awarding Plaintiff: (1) the temporary and permanent injunctive relief requested above; (2) statutory damages as described above; (3) costs; (4) reasonable and necessary attorneys' fees; and (5) all other relief the Court deems appropriate.

Respectfully submitted,

J. BRUCE SCRAFFORD
State Bar No. 17931100
bscrafford@abaustin.com
ARMBRUST & BROWN, PLLC
100 Congress Avenue, Suite 1300
Austin, Texas 78701
(512) 435-2300 – telephone
(512) 435-2360 – facsimile

ATTORNEYS FOR PLAINTIFF

CERTIFICATE OF NOTICE

I certify that to the best of Plaintiff's and Plaintiff's counsel's knowledge, Defendant Spectra254, LLC is not represented by Texas counsel in this matter. Before filing Plaintiff's Original Petition And Application For Temporary Restraining Order And Temporary Injunction, I emailed a courtesy copy of the document to Defendant's CEO, George Lichtblau, and advised him of Plaintiff's intent to seek a Temporary Restraining Order in Bexar County District Court on the afternoon of December 22, 2014, and requested that he contact me if he or his representative wish to participate in the hearing.

J. BRUCE SCRAFFORD

[redacted]

From: George Jay Lichtblau [mailto:gjlichtblau@gmail.com]
Sent: Thursday, November 27, 2014 7:56 AM
To: [redacted]
Subject: XENEX NOT SAFE.. Never tested for Safety UL 61010-1

XENEX Pulsed UV system never tested for Safety UL 61010-1. XENEX never tested to meet the FCC Regulations Part 18.
XENEX never publishes real independent test data to demonstrate its effectiveness in killing pathogens. WHY NOT???
XENEX never tested against Ebola!!

Spectrat254 publishes all of the independent biological test reports of its products on its web site: www.spectra254.com.

CHECK IT OUT!!

George Jay Lichtblau
Chairman and CEO
Spectra254
3 Corporate Drive
Danbury, Ct. 06810
Email: gjlichtblau@spectra254.com

EXHIBIT 1

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Product Description

Title:	ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL & LABORATORY USE
Company:	XENEX DISINFECTION SERVICES LLC - San Antonio, TX USA
Product Information:	UV Disinfection Device, Model Nos. PX-UV3D, PX-UV3E.
Evaluated to the following:	A representative sample of the listed devices have been tested, investigated and found to comply with the requirements of the Standard(s) for Electrical Equipment for Measurement, Control & Laboratory Use; Part 1 General Requirements (CAN/CSA-C22.2 No. 61010-1) and are identified with the cETL Listed Mark.

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(or +1-312-906-7801)
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EXHIBIT 2

AUTHORIZATION TO MARK

This authorizes the application of the Certification Mark(s) shown below to the models described in the Product(s) Covered section when made in accordance with the conditions set forth in the Certification Agreement and Listing Report. This authorization also applies to multiple listee model(s) identified on the correlation page of the Listing Report.

This document is the property of Intertek Testing Services and is not transferable. The certification mark(s) may be applied only at the location of the Party Authorized To Apply Mark.

Applicant:	Xenex Healthcare Svcs	**Manufacturer:**	Xenex Healthcare Svcs
Address:	121 Interpark Blvd, Suite 104 San Antonio, TX 78216	**Address:**	121 Interpark Blvd, Suite 104 San Antonio, TX 78216
Country:	USA	**Country:**	USA
Contact:	Sharon Burns	**Contact:**	Sharon Burns
Phone:	800-553-0069	**Phone:**	800-553-0069
FAX:	NA	**FAX:**	NA
Email:	Sharon.Burns@Xenex.com	**Email:**	Sharon.Burns@Xenex.com

Party Authorized To Apply Mark: Same as Manufacturer
Report Issuing Office: Dallas, TX

Control Number: 4004806 **Authorized by:** _____

for Thomas J. Patterson, Certification Manager

Intertek

This document supersedes all previous Authorizations to Mark for the noted Report Number

This Authorization to Mark is for the exclusive use of Intertek's Client and is provided pursuant to the Certification agreement between Intertek and its Client. Intertek's responsibility and liability are limited to the terms and conditions of the agreement. Intertek assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Authorization to Mark. Only the Client is authorized to permit copying or distribution of this Authorization to Mark and then only in its entirety. Use of Intertek's Certification mark is restricted to the conditions laid out in the agreement and in this Authorization to Mark. Any further use of the Intertek name for the sale or advertisement of the tested material, product or service must first be approved in writing by Intertek. Initial Factory Assessments and Follow-up Services are for the purpose of assuring appropriate usage of the Certification mark in accordance with the agreement; they are not for the purposes of production quality control and do not relieve the Client of their responsibility in this respect.

Intertek Testing Services NA Inc
545 E. Algonquin Road, Arlington Heights, IL 60005
Telephone 800-345-3851 or 847-439-5667 Fax 847-439-7320

Standard(s):	Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements, ANSI/UL 61010-1 and CAN/CSA C22.2 No. 61010-1, Ed: 2nd, Issue: 07/12/2004, Rev: 10/28/2008
Product:	UV Disinfection Device
Brand Name:	Xenex
Models:	PX 426i

EXHIBIT 3

ATM Issued: 5/15/12

ED 16.2.15 (8-Jan-13) Mandatory

Jinadatha et al. BMC Infectious Diseases 2014, 14:187
http://www.biomedcentral.com/1471-2334/14/187

BMC Infectious Diseases

RESEARCH ARTICLE Open Access

Evaluation of a pulsed-xenon ultraviolet room disinfection device for impact on contamination levels of methicillin-resistant *Staphylococcus aureus*

Chetan Jinadatha[1*], Ricardo Quezada[2], Thomas W Huber[1], Jason B Williams[3], John E Zeber[1,2] and Laurel A Copeland[1,2]

Abstract

Background: Healthcare-acquired infections with methicillin-resistant *Staphylococcus aureus* (MRSA) are a significant cause of increased mortality, morbidity and additional health care costs in United States. Surface decontamination technologies that utilize pulsed xenon ultraviolet light (PPX-UV) may be effective at reducing microbial burden. The purpose of this study was to compare standard manual room-cleaning to PPX-UV disinfection technology for MRSA and bacterial heterotrophic plate counts (HPC) on high-touch surfaces in patient rooms.

Methods: Rooms vacated by patients that had a MRSA-positive polymerase chain reaction or culture during the current hospitalization and at least a 2-day stay were studied. 20 rooms were then treated according to one of two protocols: standard manual cleaning or PPX-UV. This study evaluated the reduction of MRSA and HPC taken from five high-touch surfaces in rooms vacated by MRSA-positive patients, as a function of cleaning by standard manual methods vs a PPX-UV area disinfection device.

Results: Colony counts in 20 rooms (10 per arm) prior to cleaning varied by cleaning protocol: for HPC, manual (mean = 255, median = 278, q1-q3 132–304) vs PPX-UV (mean = 449, median = 365, q1-q3 332–530), and for MRSA, manual (mean = 127; median = 28.5; q1-q3 8–143) vs PPX-UV (mean = 108; median = 123; q1-q3 14–183). PPX-UV was superior to manual cleaning for MRSA (adjusted incident rate ratio [IRR] = 7; 95% CI <1-41) and for HPC (IRR = 13; 95% CI 4–48).

Conclusion: PPX-UV technology appears to be superior to manual cleaning alone for MRSA and HPC. Incorporating 15 minutes of PPX-UV exposure time to current hospital room cleaning practice can improve the overall cleanliness of patient rooms with respect to selected micro-organisms.

Keywords: MRSA, Methicillin-resistant *Staphylococcus aureus*, No touch disinfection, Pulsed xenon ultraviolet disinfection device, Nosocomial infections

* Correspondence: Chetan.Jinadatha@va.gov
[1]Central Texas Veterans Health Care System, Temple, Texas 76504, USA
Full list of author information is available at the end of the article

EXHIBIT 4

Background

Healthcare-acquired infection (HAI) with methicillin-resistant *Staphylococcus aureus* (MRSA) is a significant cause of mortality and morbidity in the United States accounting for up to $9.7 billion annually in additional health care costs, and €44.0 million annually in Europe [1,2]. In the Americas, Europe, and parts of Africa and Asia, MRSA is the predominant multi-drug resistant microbe, making it a global concern of escalating importance in terms of cost and patient safety [3]. Combating MRSA with new pharmaceutical agents offers only short-term solutions; unconventional approaches may comprise a more effective solution to drug-resistant infectious microbes [4].

Patients admitted to rooms vacated by MRSA-positive patients have higher relative risk of acquiring MRSA [5,6]. In a 2009 review of environmental cleaning studies, Dancer concluded that high-touch surfaces present one of the biggest risks of MRSA acquisition for patients, providing a source of direct infection to patients and of indirect infection via healthcare workers [7]. Decontaminating high-touch surfaces could prevent HAI [8]. Manual cleaning with approved disinfectants is the current standard of disinfection in most countries including the United States, and this requires supervision with constant reinforcement and education of environmental management service (EMS) staff to maintain effectiveness [9].

Surface decontamination technologies that utilize ultraviolet light or hydrogen peroxide may be effective at reducing microbial burden, possibly with greater consistency than is achieved with manual methods [10-13]. Portable pulsed xenon ultraviolet (PPX-UV) technology uses high-intensity broad-spectrum UV irradiation in the 200–320 nm range. UV breaks the molecular bonds in DNA, thereby destroying the organism and spores in laboratory settings [12,14]. Spores from *Clostridium difficile* (c.diff) are killed by 185–230 nm UV irradiation, overlapping the range of the PPX-UV [15].

The efficacy of PPX-UV in hospitals in comparison to manual cleaning has not been demonstrated. The purpose of this study was to compare standard manual room-cleaning to PPX-UV disinfection technology for MRSA and bacterial heterotrophic plate counts (HPC) on high-touch surfaces in patient rooms.

PPX-UV device

We used a portable PPX-UV device (Xenex Healthcare Services, San Antonio, TX) measuring 30 L × 20 W × 38 H inches (Figure 1). The device is used in empty patient rooms after discharge as prolonged exposure to UV can cause skin and eye irritation. The device used in this study housed a bulb twice as intense as in the device described by Stibich and colleagues [10], and it had new features such as a data logger, reflector, and UV pass filter. The data log recorded room number, user ID, time, date, number of pulses, amount of energy emitted and any error codes. The reflector was mounted on a column housing the xenon gas bulb emitting the pulsed UV rays. While column moved up and down during a 5-minute cycle, the reflector optimized the UV rays downward to high-touch surfaces. A UV pass filter blocked visible light while allowing UV-C to pass, making it less disturbing to the naked eyes when PPX-UV runs behind glass without curtains. UV is less effective in areas that are out of the direct line of sight; hence separate cycles for each area are recommended with 2 cycles around the patient's bed. In a typical patient room with living room and separate bathroom, a 5-minute cycle in three different positions is recommended plus 2–3 minutes for positioning for a total of 18 minutes per room (Figure 2). The device emitted ~450 flashes/cycle. The device requires

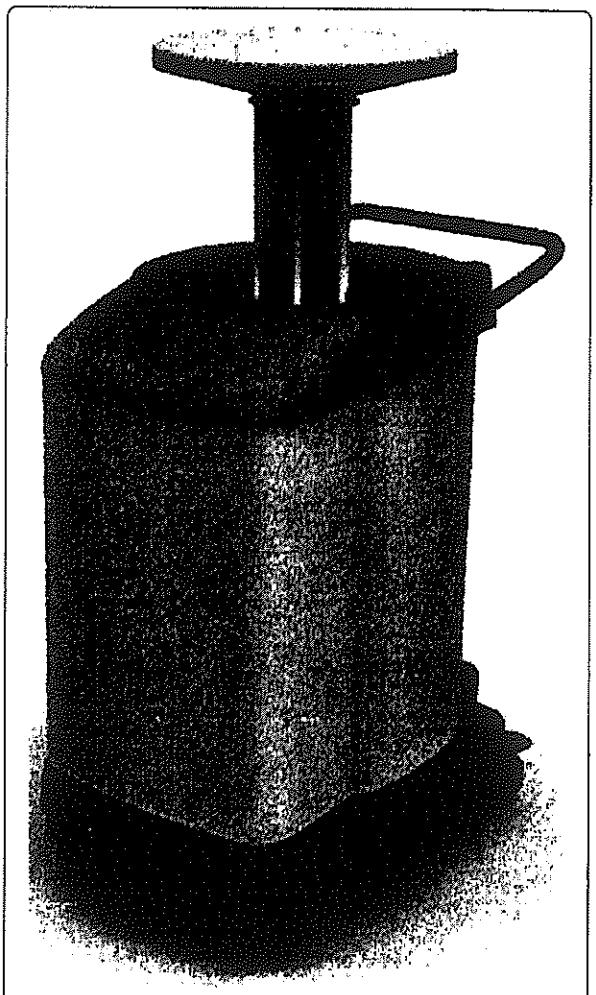

Figure 1 Photograph of the PPX-UV device.

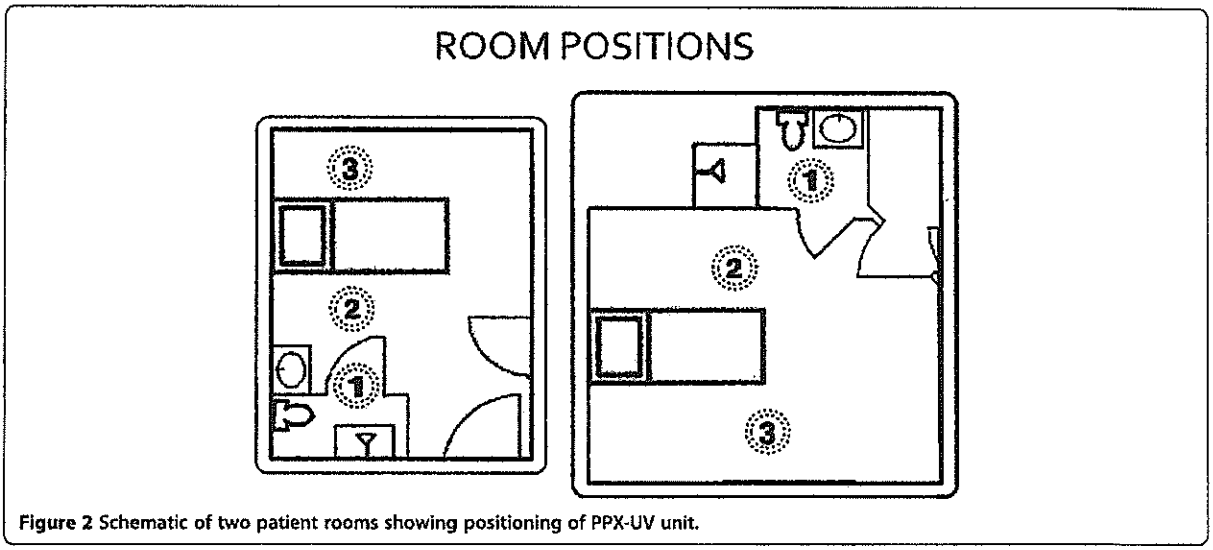

Figure 2 Schematic of two patient rooms showing positioning of PPX-UV unit.

positioning prior to each 5-minute cycle, so that it is necessary to have an operator in the vicinity. The device was easy to set up and operate per EMS staff operating it.

Methods

This comparative study was conducted January-February 2012 in the Central Texas Veterans Health Care System, Temple, TX with approval from its institutional review board. We are a 120-bed acute care hospital. In the facility studied, all patients undergo nasal swab at admission, transfer and discharge; these samples are tested for MRSA by polymerase chain reaction (PCR) (at admission) or culture (transfer/discharge) as a routine process of care according to institutional policy. Patients with MRSA infection either community acquired or hospital acquired are identified by culturing suspicious body site or body fluids. Individuals with MRSA detected by PCR or culture or with prior-year positive PCR/culture are placed on contact isolation during their entire hospitalization. We studied rooms vacated by patients that had a MRSA-positive PCR or culture during the current hospitalization and at least a 2-day stay.

Samples from five high-touch surfaces (bedrail, toilet seat, bathroom handrail, call button, tray table) were collected using Rodac plates, before terminal cleaning of rooms vacated by a patient on isolation for MRSA. For non-flat surfaces such as handrail, contact plates were rolled so that the entire surface was contacted. The rooms were then treated according to one of two protocols: standard manual cleaning or PPX-UV.

In the first group (manual arm; n = 10), rooms were cleaned using the standard procedures. Standard manual cleaning included cleaning visible dirt then soak and-wipe cleaning with Dispatch® (The Clorox Company, Oakland, CA) disinfection solution. Dispatch® is a pre-mixed, ready-to-use 1:10 bleach solution with a contact time of 1 minute for killing bacteria. EMS personnel used cotton rags soaked in this pre-mixed solution with one to two applications and passes for all areas and surfaces in a patient room regardless of soiling. On an average, EMS personnel used 3–4 rags per room. These multiuse rags were then laundered for later use in another room. This included all the walls in bathroom and living room up to head height. EMS personnel replaced curtains if present.

In the second group (PPX-UV arm; n = 10), the room was pre-cleaned using same process described in the manual arm using Dispatch® except the focus was to clean only the visibly soiled surfaces instead of every surface in the room to achieve an aesthetic clean vs the thorough cleansing of the manual arm thus saving valuable turnaround time. Then the PPX-UV device was deployed according to manufacturer's protocol. We then collected our post-cleaning samples ensuring that Dispatch® had completely dried of the sampling surface. Finally, the PPX-UV rooms were cleaned manually per standard protocol (similar to manual arm) to meet requirements for the healthcare facility.

Post-cleaning samples were taken from surface locations immediately adjacent to the pre-cleaning sample locations. In the PPX-UV arm the sampling took place immediately after completion of the PPX-UV cycles for the room. The Rodac sample plates were transported on icepack-lined shipping containers by overnight courier to Antimicrobial Test Laboratories (ATL), an independently contracted microbiology laboratory in nearby Round Rock, Texas. Available rooms were included if they met study criteria (MRSA-positive patient vacating;

sufficient time for shipping that day); they were randomly assigned to either manual or PPX-UV arm. In order to ensure next-day delivery, no samples were collected after the final shipper's pick-up time of 7 pm. The microbiologist at ATL was blinded to protocol arm. EMS personnel were aware of the fact that samples were being collected pre- and post-cleaning but were not aware of specific surfaces from which samples were being collected.

Environmental testing procedure

TSA supplemented with Lecithin and Tween 80 (neutralizes bleach) and HardyCHROM MRSA Rodac contact plates (Hardy Diagnostics, Santa Maria, CA) were received at ATL approximately 18–24 hours after sampling. All samples were given specific identification numbers prior to incubation. HPC and MRSA contact plates were incubated for 48 ± 4 hours at 30 ± 2°C and 36 ± 1°C, respectively, and individual colonies counted immediately after incubation. Every colony, regardless of color or morphology, was recorded for HPC counts. The target organism MRSA was morphologically identified (deep pink to magenta-colored colonies), and regardless of size, were recorded for MRSA counts per package insert from Hardy Diagnostics. Further MRSA colonies were then subcultured and identified using standard microbiological methods. Contact plates resulting in confluent growth were designated as too numerous to count (TNTC) for reporting purposes. TNTC and any plates with a colony count of 250 or higher for MRSA or HPC were assigned a value of 250 colonies.

Measures and analysis

We assessed counts of MRSA and HPC for each of 20 rooms, summing samples taken from the five different surfaces to create total MRSA and total HPC counts, respectively, for pre- and post-cleaning measures (four variables in all). Additional measures were individual surface counts, surface type, microbe type (HPC; MRSA), cleaning time in minutes, and room size in square meters. The independent variable of primary interest was cleaning protocol (manual vs PPX-UV). Colony counts were described with means, medians and the interquartile range (q1-q3). Colony count reductions were calculated as the percent change from pre-cleaning to post-cleaning. Baseline counts were not equivalent per Wilcoxon Rank Sum test, therefore adjusting for the pre-cleaning counts was appropriate. Post-cleaning colony counts were modeled as a function of baseline count and cleaning protocol. Poisson regression is appropriate for modeling count data where the mean is equal to the variance, however, when the data are over-dispersed as these were with the variance greatly exceeding the mean, Poisson regression will under-estimate the standard errors whereas negative binomial regression produces more accurate estimates [16]. Therefore, we used negative binomial regression to estimate the association of cleaning protocol (manual vs PPX-UV) with final colony count, adjusting for baseline counts. The strength of association between predictor and outcome is reported as a regression coefficient for change in the log of counts when the factor is present, and can be exponentiated as an incident rate ratio with 95% confidence interval (IRR, CI95). The IRR is similar to the more familiar odds ratio where a significant effect is one whose CI95 excludes 1. The IRR is the factor by which the expected colony count is multiplied per 1-unit increase in the predictor. For the cleaning protocol, the predictor was either 0 (PPX-UV) or 1 (manual cleaning).

Results

Colony counts in 20 rooms (10 per arm) prior to cleaning varied by cleaning protocol: for HPC, manual (mean = 255, median = 278, q1-q3 132–304) vs PPX-UV (mean = 449, median = 365, q1-q3 332–530), and for MRSA, manual (mean = 127; median = 28.5; q1-q3 8–143) vs PPX-UV (mean = 108; median = 123; q1-q3 14–183). These baseline plate counts were not equivalent and were not normally distributed. After cleaning, the counts averaged 60 colonies (76% reduction; manual) vs 8 colonies (98% reduction; PPX-UV) for HPC, and 11 colonies (91% reduction; manual) vs 1 colony (99% reduction) for MRSA. The HPC count was significantly greater for the manual cleaning arm relative to the PPX-UV arm, adjusting for baseline total HPC counts in the rooms (IRR = 12.9, CI95 3.5-47.8, $p < .01$), meaning the expected count was multiplied by a factor of 13 when the independent variable increased by one unit from 0 (machine) to 1 (manual). Similarly, the MRSA count was significantly higher in the manual cleaning arm relative to the PPX-UV arm (IRR = 7.2, CI95 1.3-41.4, $p < .03$). See Tables 1, 2 and 3. The majority of the difference in post-cleaning colonies was due to high residual counts on the toilet seats in the manual arm. The number of MRSA-positive sites per room after manual cleaning was 0 (4 rooms), 1 (4 rooms), or 2 (2 rooms), and the number of MRSA-positive sites per room after PX-UV cleaning was 0 (7 rooms), 1 (2 rooms), or 2 (1 room). The average number of minutes spent cleaning a room was 49 minutes including device time (SD = 13) for PPX-UV and 63 minutes (SD = 29) for manual cleaning (t-statistic = 1.5; df = 12.1; $p = .17$, n.s.). The average size of a patient room (living & bathroom) in the manual arm was 23 m^2 and in the PPX-UV arm was 25 m^2.

Discussion

Our study showed that a "no-touch" semi-automated system, the PPX-UV, was effective in substantially

Table 1 Methicillin-resistant *Staphylococcus aureus* and bacterial heterotrophic plate counts before and after disinfection per room for five high-touch surfaces total

	Colony count measures of central tendency and variability by room mean; median (IQR)		
	Before	After	Reduction
HPC			
Manual arm	255.0; 278.0 (132-304)	60.4; 31.0 (15-70)	76.3%
PPX-UV arm	449.0; 364.5 (332-530)	8.4; 4.0 (1-10)	98.1%
	Before	**After**	
MRSA			
Manual arm	127.3; 28.5 (8-143)	11.3; 1.0 (0-4)	91.1%
PPX-UV arm	108.2; 123.0 (14-183)	0.7; 0.0 (0-1)	99.4%

HPC: Bacterial heterotrophic plate counts.
MRSA: Methicillin-resistant *Staphylococcus aureus*.
PPX-UV: Portable pulsed xenon ultraviolet.

reducing the heterotrophic bacterial and MRSA burden on high-touch surfaces in rooms vacated by MRSA-positive patients. PPX-UV disinfection may add to the armamentarium against HAI's without risking the adaptive genetic resistance incurred by pharmaceutical weapons. Implementation including training EMS personnel to operate the device was minimal, and time spent cleaning was not increased. Because there were separate cycles for bathroom and living room, the surface reduction in aerobic colony counts may be better than with other UV systems; a head-to-head comparison of UV area disinfection devices may be warranted [12,13].

Consistency in patient room-cleaning is needed. High residual colony counts were observed on the toilet seats post-cleaning in the manual arm. This may be due to human inconsistency or memory failure regarding which parts of the room have been cleaned, a common problem with repetitive tasks. A highly structured approach that involves educational, procedural, and administrative interventions with repeated performance feedback to EMS by monitoring the thoroughness of cleaning with either adenosine 5'-triphosphate (ATP) assays or fluorescent dyes has been shown to be successful in reduction of microbial contaminants in patient rooms [17,18]. Other intervention programs such as monitoring room cleanliness using checklists may also result in significant improvement in cleaning practices [19]. Although such interventions improve cleaning, in the post-intervention period the increase is no more than 85% [20], and the effects may decrease post-intervention unless ongoing feedback to environmental services staff is sustained [9]. Thus empowering EMS with a "no touch" semi-automated system such as PPX-UV to substantially reduce the microbial burden on high-touch surfaces, combined with education and feedback, may help us achieve the desired effect of thorough disinfection for every vacated patient room. Training on the device was simple; EMS personnel commented they could easily incorporate this system into their routine cleaning practices. The usual run time of PPX-UV was 15 minutes and required 2–3 minutes of additional setup time. Hence the authors believe PPX-UV disinfection could be integrated into routine hospital cleaning operations without disruption of patient flow or undue burden on EMS staff.

Our study adds to the existing debate in literature about one long cycle vs several shorter cycles for UV disinfection and about a UV device's effect on aerobic surface colony count reduction. Since separate cycles are needed for bathroom and two positions for living room, the surface reduction in aerobic colony counts was similar to studies of other UV systems that had separate

Table 2 Estimated effect of cleaning protocol on colony counts: manual cleaning vs portable pulsed ultraviolet machine cleaning (N = 20 rooms)

Type of colonies	Regression coefficient (beta)	95% CI for beta	Incident rate ratio (exp(beta))	95% CI for IRR	Chi-square statistic	Pr
MRSA						
Baseline count	0.004	<0.0-0.001	–		3.24	0.07
Manual cleaning	2.0	0.2-3.7	7.2	1.3-41.4	4.91	0.03
HPC			–			
Baseline count	0.002	<0.0-0.01			1.49	0.22
Manual cleaning	2.6	1.3-3.8	12.9	3.5-47.8	14.7	<.01

Table 3 Total positive plates & colony counts per site by bacterial heterotrophic colony counts and methicillin-resistant *Staphylococcus aureus* before and after manual and UV light disinfection for 5 high touch surfaces

Site	HPC positive plates (colony count)				MRSA positive plates (colony count)			
	Manual		PPX-UV		Manual		PPX-UV	
	Before	After	Before	After	Before	After	Before	After
Bed rail	10/10 (774)	10/10 (30)	10/10 (1079)	0/10 (0)	8/10 (308)	0/10 (0)	8/10 (188)	0/10 (0)
Call button	10/10 (494)	6/10 (64)	10/10 (1121)	3/10 (54)	9/10 (89)	1/9 (1)	8/10 (286)	1/10 (1)
Tray table	10/10 (311)	8/10 (21)	10/10 (293)	1/10 (4)	9/10 (48)	1/10 (1)	5/10 (10)	1/10 (1)
Bathroom handrail	10/10 (392)	10/10 (91)	10/10 (988)	5/10 (20)	8/10 (269)	3/10 (86)	9/10 (265)	2/10 (5)
Toilet seat	10/10 (579)	7/10 (398)	10/10 (1009)	2/10 (6)	9/10 (559)	3/10 (25)	8/10 (333)	0/10 (0)
Total	50/50 (2550)	41/50 (604)	50/50 (4490)	11/50 (84)	43/50 (1273)	8/49 (113)	38/50 (1082)	4/50 (7)

HPC: Bacterial heterotrophic plate counts.
MRSA: Methicillin-resistant *Staphylococcus aureus*.
PPX-UV: Portable pulsed xenon Ultraviolet.

bathroom cycles and perhaps better surface reduction as compared to studies with no separate bathroom cycles [11-13]. In the PPX-UV arm, the focus was to get the rooms aesthetically clean by manually wiping all grossly soiled surfaces. We believed that our efforts to focus on the aesthetic cleaning, thus allowing for a truncated pre-cleaning routine is consistent with new published literature. Anderson et al. showed that despite lack of pre-cleaning there was statistically significant reduction in organisms such as VRE and C.diff spores [21]. Zhang et al. also showed that the organic material from the hospital rooms only modestly affected UV killing of spores [22]. The above research findings could explain why PPX-UV arm had lower counts inspite of a truncated pre-cleaning routine. The manufacturer recommended the same cycle times for patient rooms with c. diff spores based on preliminary lab data, and studies are underway at another site to examine the efficacy on c. diff spores in a hospital setting, however, future independent research should directly assess sporicidal capacity of the PPX-UV. Federally funded multi-site comparative study with multiple microbial targets is currently underway. Future research should also assess patient outcomes and cost-effectiveness for major and emergent infectious agents in healthcare systems with and without systematic PPX-UV cleaning.

Our study has several limitations: it was not designed to assess impact on the actual transmission of healthcare-acquired infections. The number of surfaces and rooms sampled was small but similar in size to previously published studies [11,12]. The protocol did not evaluate the incremental impact of UVC treatment following routine cleaning, a process to be evaluated in our next study. The delay to culture introduced by the overnight transport process may have influenced culture viability, however, both manual and PPX-UV samples experienced the same transport periods thus reducing likelihood of bias from this source of variability. EMS personnel were not blinded to the study nor to the protocol to be used in each room. Supervisors commented that they were taking longer than usual to clean the rooms, suggesting increased vigilance; this would potentially bias our results toward the null. Better differential effects might be achieved in a real-world implementation where lapses in EMS attentiveness may occur unpredictably. The rather high post-cleaning MRSA counts in the manual cleaning arm may point to another area of research, comparing the quality of manual cleaning protocols across hospital systems. It is possible that higher bacterial counts in the manual arm may be due to lack of actual manual cleaning process rather than the lack of efficacy of the manual cleaning process. While it is possible that ours is the only facility in the VA system whose cleaning crew has inconsistency in cleaning thoroughness, we suspect it is more a part of the human condition. Two multisite trials that we know of are currently in progress and should provide larger scale results on PPX-UV effectiveness.

Conclusions

In conclusion, PPX-UV technology appears to be superior to manual cleaning alone for MRSA and HPC. We believe incorporating 15 minutes of PPX-UV exposure time to current hospital room cleaning practice can improve the overall cleanliness of patient rooms with respect to selected micro-organisms by a factor of 7–12 in a sustainable manner. Outcome studies are being conducted to assess the economic and clinical impact of this technology.

Competing interests
This study's laboratory activity including use of the PPX-UV machine was supported by a grant from Xenex Healthcare Services, LLC. No author has identified a competing interest regarding the study beyond working for the institution studied (Department of Veterans Affairs, Veterans Health Administration).

Authors' contributions
All authors made a significant contribution to the project. CJ and RQ developed the methodology, protocol, performed data collection and manuscript preparation. TH and JW carried out the microbiology and contributed to the manuscript. JZ and LC participated in statistical analysis and contributed to the manuscript. All authors read and approved the final manuscript.

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Brief report

The effect of portable pulsed xenon ultraviolet light after terminal cleaning on hospital-associated *Clostridium difficile* infection in a community hospital

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There is evidence that contamination of patient rooms from previous occupants is associated with hospital-associated *Clostridium difficile* infection (HA-CDI). During January 2011, the use of 2 portable pulsed xenon ultraviolet light devices (PPX-UV) to disinfect patient rooms was added to routine hospital discharge cleaning in a community hospital. In 2010, the HA-CDI rate was 9.46 per 10,000 patient-days; in 2011, the HA-CDI rates was 4.45 per 10,000 patient-days (53% reduction, $P = .01$). The number of deaths and colectomies attributable to hospital-associated *C difficile* infection also declined dramatically.

There is mounting evidence that contamination of patient rooms from previous occupants is associated with hospital-associated *Clostridium difficile* infection (HA-CDI).[1,2] A number of environmental interventions have been introduced to attempt to decrease *C difficile* transmission within hospitals. Although guidelines published by the Society for Healthcare Epidemiology of America (SHEA)[3] for CDI were followed in our hospital, CDI remained a concerning clinical issue These guidelines include, for *C difficile* rooms, the use of chlorine-based agents for daily and terminal cleaning of rooms where patients with *C difficile* are housed, contact precaution measures for the duration of the hospital stay, and use of soap and water for hand hygiene. We had also implemented enhanced education on improved cleaning techniques and competency evaluations for our environmental services (ES) workers prior to the use of the ultraviolet (UV) light.

Rutala and Weber[2] state that "new technologies hold the promise for improved disinfection of rooms with *C difficile* surface contamination." Specifically, both Rutala et al[4] and Nerandzic et al[5] showed that UV light treatment has the potential to lower environmental *C difficile* contamination levels in patient rooms. Both Boyce et al[6] and Stibich et al[7] demonstrated the effectiveness of portable UV light devices on deactivating *C difficile* endospores. To date, however, no one has demonstrated clinical impact on facility-wide HA-CDI with the use of automated environmental decontamination technology. We report a significant decrease in the HA-CDI rate, as well as in the number of both CDI-related deaths and CDI-related colectomies after hospital-wide implementation of portable pulsed xenon UV (PPX-UV).

METHODS

Cooley Dickinson Hospital is a 140-bed acute care community hospital in western Massachusetts with mostly single-bed rooms. During January 2011, the use of 2 PPX-UV devices (Xenex Healthcare Services, San Antonio, TX) to disinfect patient rooms was introduced. Rooms and bathrooms were terminally cleaned as usual with a hospital-grade disinfectant product (ph7Q Ultra; Betco Corporation, Toledo, OH) in most rooms and a chlorine-based product (Clorox Clean-up and Clorox Germ Wipes; The Clorox Company, Oakland, CA) in *C difficile* rooms. This was followed by the use of PPX-UV, for three 7-minute exposures (once in the bathroom and then in 2 locations in the main patient room). The overall room turn-over time was extended by approximately 15 minutes over a standard terminal cleaning because cleaning could continue in the main room during PPX-UV treatment of the bathroom.

PPX-UV devices were also used in the operating suites (nights), emergency department (early mornings), and other clinical areas as available. Surveillance for HA-CDI (hospital onset plus community onset) using SHEA definitions[3] continued as per Infection

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EXHIBIT 5

Prevention Department routine. No environmental sampling was performed.

Description and cost of the device

The PPX-UV device contains a xenon flash lamp that emits a broad spectrum of light covering the germicidal, or ultraviolet-C (UV-C), spectrum of 200 to 280 nm as well as the visible light spectrum. The device weighs approximately 150 pounds and is approximately 20 inches wide by 30 inches long by 38 inches high. The PPX-UV system produces a pulsed flash at a frequency of 1.5 Hz with an approximate output of 505 J per pulse and a duration of less than 360 μs. The device is operated remotely by ES personnel in the hallway just outside the patient room and includes safety features such as motion sensors, which turn off the device if the door is opened. The operating time for the device for *C difficile* deactivation was 7 minutes per position. Leasing 2 machines cost less than $5,000 per month.

Baseline infection prevention policies and ES procedures

Throughout the study period, our policy followed SHEA guidelines including use of chlorine-based agents for terminal cleaning of *C difficile* rooms, use of soap and water for hand hygiene, and contact precautions for the duration of the hospital stay. Patients were put on contact precautions when *C difficile* infection was suspected but not necessarily proven. Adherence to policy was not measured. No new infection prevention policies or protocols were pursued during the intervention year.

There was no real-time antibiotic stewardship before or during the intervention. However, ciprofloxacin was added to the formulary in early 2010, with a decline in levofloxacin use and total quinolone use. As noted in Table 1, levofloxacin use (adjusted for patient-days) declined 38.6% with a rise in ciprofloxacin use, and total quinolone use declined 14.8% during the year prior to the intervention. During the intervention year, levofloxacin use continued to fall, although more modestly, and total quinolone use fell minimally. No new formulary initiatives were pursued during the intervention year.

In the previous 2 years, ES workers were educated to standardize cleaning practices and were taught about the role of environmental contamination in transmitting infections. In addition, an improved communication system (using beeper messages to alert ES staff when a room needed to be cleaned) was implemented to increase efficiency in room turnover and to inform housekeepers when chlorine-based products were needed.

PPX-UV implementation

The PPX-UV device utilization was prioritized as follows: discharged contact precaution rooms, intensive care unit rooms, and other medical/surgical/labor and delivery rooms (with the goal of using the PPX-UV device in every room after patient discharge), and in operating rooms, emergency department rooms, and on shared medical equipment when possible. No new ES workers were hired to implement this protocol.

Testing for and diagnosing C difficile

In early 2009 in-house testing for *C difficile* was changed from a toxin A-only enzyme immunoassay card test to the Meridian Immunocard Toxins A and B (Meridian, Charlotte, NC), with occasional use of a send-out polymerase chain reaction (PCR) test (Real-time PCR using LightCycler and Fluorescent Resonance Energy Transfer; Mayo, Rochester, MN). In 2011 results from (more frequently used) PCR tests were also included in the data. The definition we used for HA-CDI[3] did not change over the study periods. Genotyping was not performed.

Table 1
Quinolone use 2009-2011

Year	Quinolone-days	Quinolone-days/patient-days × 100 (Q/P)	Percent change (Q/P) from previous year
2009			
Ciprofloxacin-days	88.5	0.24	
Levofloxacin-days	4,848	13.2	
Total quinolone-days	4,936.5	13.5	
2010			
Ciprofloxacin-days	1,215.5	3.5	+1,358%
Levofloxacin-days	2,819	8.1	−38.6%
Total quinolone-days	4,034.5	11.5	−14.8%
2011			
Ciprofloxacin-days	1,527.5	4.5	+28.5%
Levofloxacin-days	2,265	6.7	−17.3%
Total quinolone-days	3,792.5	11.2	−2.6%

NOTE. Ciprofloxacin-days = ciprofloxacin doses administered divided by 2. Levofloxacin-days = levofloxacin doses administered. Quinolone-days = ciprofloxacin days + levaquin days.

Statistical analysis

HA-CDI rates were compared using a 1-tailed *t* test calculated using Stata Data Analysis and Statistical Software (STATA Corp, College Station, TX).

RESULTS

HA-CDI rates

The HA-CDI rate per 10,000 patient-days was reduced from 9.46 in 2010 to 4.45 in 2011 (53% reduction; $P = .01$; 95% confidence interval: 6.40-12.4; $t = 2.491$). Previously rates were stable at an average of 9.22 for the years 2008 to 2010 (compared with 2011, 52% reduction; $P = .002$; 95% confidence interval: 7.58-10.8; $t = 2.97$). It should be noted that, of the 15 patients who were diagnosed with HA-CDI in 2011, 11 (73%) were placed in rooms that had *not* been treated with the PPX-UV device prior to occupation. Overall, 56% of discharged rooms received the UV light treatment. One reason some rooms were not treated was the simultaneous discharge of a number of patients and the limited number of devices. In addition, whereas most of our rooms are single occupancy, occasionally 2-bed rooms with 1 patient remaining could not be fully treated, although often the bathroom was treated. The at-risk population at our facility had a fairly stable median age (57.5-58.4 years), and our patient acuity index rose slightly (see Table 2).

Death and colectomy

During 2011, there was 1 attributable death, and there were no attributable colectomies, whereas there were 6 and 3, respectively, in 2010; 8 and 1, respectively, in 2009; and 4 and 1, respectively, in 2008.

DISCUSSION

The HA-CDI rate in 2011, during the use of PPX-UV, was significantly lower than during the previous 1 year and than the average of the previous 3 years. The inclusion of PCR data in 2011 would have increased our rate of positive tests, if all other factors were the

Table 2
Annual hospital and *C difficile* data

	2008	2009	2010	2011
Number HA-CDI patients	32	36	33	15
Number HA-CDI attributable deaths	4	8	6	1
Number HA-CDI attributable colectomies	1	1	3	0
Rate HA-CDI per 10,000 patient-days	8.36	9.85	9.46	4.45*
Rate of death for HA-CDI patients (number deaths/total HA-CDI)	0.13	0.22	0.18	0.067
Rate of colectomy for HA-CDI patients (number colectomies/total HA-CDI)	0.03	0.03	0.09	0.0
Number of community-associated CDI (inpatient and outpatient)	46	66	62	58
Percentage of discharge rooms treated with PPX-UV	0	0	0	56
Number (%) of HA-CDI patients whose rooms were *not* treated with PPX-UV prior to admission	32 (100)	36 (100)	33 (100)	11 (73)
Hospital patient-days	38,263	36,540	34,870	33,687
Hospital average age	57.9	58.4	57.5	58.3
Hospital acuity index (Diagnosis-related group case weight, Centers for Medicare and Medicaid Services)	0.0953	1.1265	1.1315	1.1386

*Comparison of HA-CDI rate in 2010 vs 2011: 53% reduction, $P = .01$; 95% confidence interval: 6.40-12.4; $t = 2.491$. The average HA-CDI rate for 2008-2010 was 9.22. Comparison of this rate with 2011 rate: 52% reduction; $P = .002$; 95% confidence interval: 7.58-10.8; $t = 2.97$.

same, thus making a change in data collection or testing unlikely to have accounted for our results. Hospital average age and acuity index increased slightly between 2010 and 2011, which probably would have increased patient risk for HA-CDI (see Table 2).

Because antibiotic use—in particular levofloxacin—may be a risk factor for the development of HA-CDI,[8] our quinolone usage was evaluated (see Table 1). Total quinolone use fell prior to the implementation of PPX-UV but remained relatively stable between the 1 year prior and the intervention year. Interestingly, levofloxacin use declined significantly during the previous 1 year (2010) without a major change in HA-CDI compared with the prior year (2009). Levofloxacin use continued to decline modestly in the study year, with a rise in ciprofloxacin use compared with the previous year. Given that a dramatic decline in levofloxacin use did not appear to affect the HA-CDI rate between 2009 and 2010, it appears unlikely that further changes in quinolone use accounted for the significant change in HA-CDI during the study year.

The total number of HA-CDI-related deaths and colectomies decreased substantially, with no colectomies attributable to HA-CDI occurring during the intervention year. Additionally, the rate of death because of HA-CDI declined. This may be attributable to the decrease in number of cases and/or to the severity of cases.

Whereas the goal was to use PPX-UV in every room at terminal cleaning, discharges often occurred simultaneously. With only 2 devices, and patients waiting to be admitted, some rooms were not treated. However, vacated precaution rooms were given priority for treatment with PPX-UV. In addition, there are approximately 30 rooms that may have double occupancy when the census is high. Because people should not be exposed to the PPX-UV light, 2-bed rooms vacated by 1 patient but housing the second could not be treated, although in those situations ES staff often used the device in the bathroom only.

Prior to implementation of PPX-UV, ES workers were trained in the use of the device as well as the important role the workers play in preventing illness and death. Although adding PPX-UV to their routine did increase their workload, as a group they felt great pride in being a part of the infection prevention team and playing an enhanced role in patient care. Although there were some initial issues with bulb longevity, the use of PPX-UV was quickly and easily integrated into the ES work schedule without additional staff.

The quasiexperimental design of this study makes definitive declaration of cause and effect impossible. Besides a continued decrease in the use of levofloxacin and an increase in ciprofloxacin use, no other significant antibiotic usage or infection prevention policy changes were known to occur. In addition, whereas the total number of subjects under surveillance was large, the total number of subjects with HA-CDI was small. The study does reflect, however, the successful implementation of this new technology in a real-world setting, with improved patient outcomes.

The dramatic reduction in infection, death, and colectomy due to HA-CDI after PPX-UV was added to standard infection prevention interventions makes this technique well worth investigating further in a large center with well-controlled variables.

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Major article

Implementation and impact of ultraviolet environmental disinfection in an acute care setting

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Key Words:
Clostridium difficile
Multiple-drug-resistant organisms

Background: Multiple-drug-resistant organisms (MDROs) and *Clostridium difficile* (CD) are significant problems in health care. Evidence suggests that these organisms are transmitted to patients by the contaminated environment.

Methods: This is a retrospective study of the implementation of ultraviolet environmental disinfection (UVD) following discharge cleaning of contact precautions rooms and other high-risk areas at Westchester Medical Center, a 643-bed tertiary care academic medical center. Incidence rates of hospital-acquired MDROs plus CD before and during the UVD use were evaluated using rate ratios and piecewise regression.

Results: The average time per UVD was 51 minutes, and machines were in use 30% of available time. UVD was used 11,389 times; 3,833 (34%) of uses were for contact precautions discharges. UVD was completed for 76% of contact precautions discharges. There was a significant 20% decrease in hospital-acquired MDRO plus CD rates during the 22-month UVD period compared with the 30-month pre-UVD period (2.14 cases/1,000 patient-days vs 2.67 cases per 1,000 patient-days, respectively; rate ratio, 0.80; 95% confidence interval: 0.73-0.88, $P < .001$).

Conclusion: During the time period UVD was in use, there was a significant decrease in overall hospital-acquired MDRO plus CD in spite of missing 24% of opportunities to disinfect contact precautions rooms. This technology was feasible to use in our acute care setting and appeared to have a beneficial effect.

Multiple-drug-resistant organisms (MDROs) and *Clostridium difficile* (CD) are significant problems in health care. Evidence suggests that these organisms are transmitted to patients by the contaminated environment. Patients occupying a room that previously housed a patient with vancomycin-resistant *Enterococcus* (VRE),[1,2] methicillin-resistant *Staphylococcus aureus* (MRSA),[2] or CD infection[3] are at increased risk for acquisition of these organisms. Increased monitoring of cleaning procedures is associated with improved cleaning,[4] less environmental contamination,[2,5-8] and decreases in acquisition of VRE[9,10] and MRSA.[9]

Recently, supplemental methods for environmental disinfection, including ultraviolet light, have become available for use in patient care environments. Ultraviolet disinfection (UVD) technology uses either mercury bulb devices or pulsed xenon bulb devices. Rutala et al reported that mercury UVD reduced colony counts of MRSA and CD by more than 99% in test conditions and decreased both the number of positive cultures and the colony counts per positive culture when tested in rooms that had been occupied by patients with MRSA.[11] Boyce et al also reported significant reductions in aerobic bacterial colony counts from bedside rails, overbed tables, television remotes, bathroom grab bars, and patient bathroom toilet seats after using mercury UVD and significant reduction of CD spores with test plates located strategically in patient rooms.[12] In both studies, objects and surfaces in direct line of sight were more effectively decontaminated by UVD than areas in shadow. Although these studies have demonstrated significant reductions of bacteria in vitro and in clinical settings, there are limited studies on patient outcomes[13] or on the feasibility of use of mercury UVD in the health care environment.

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Conflicts of interest: None to report.

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EXHIBIT 6

Pulsed xenon UVD became available after mercury UVD. Literature to support the efficacy of pulsed xenon UVD in decreasing vegetative bacteria[14,15] and bacterial spores[14] indicates it is comparable with mercury UVD. In the first peer-reviewed study on patient outcomes, pulsed xenon UV was associated with a 53% decrease in CD cases in a community hospital,[16] and preliminary data demonstrated an 80% to 90% decrease in CD room contamination and decreasing trends in CD infection and VRE colonization and infection among oncology patients.[14] The purpose of this study is to describe the implementation of a pulsed xenon UVD system for environmental disinfection in an acute care setting and to quantify the rates of hospital acquired MDROs plus CD before and during UVD.

METHODS

This is a retrospective study of the implementation of UVD and the rates of hospital-acquired MDROs plus CD before and during the UVD use. The period before UVD was 30 months (January 2009-June 2011), and the UVD period was 22 months (July 2011-April 2013). This study was conducted at Westchester Medical Center, a 643-bed tertiary care hospital, near New York City. The hospital offers full services to adult and pediatric patients including specialized services for trauma, burn, neurosurgery, cardiothoracic surgery, transplant, and oncology.

The Infection Prevention and Control Department works collaboratively with Environmental Services, which is an outsourced department, to assure that cleaning protocols are appropriate. Bleach-based (sodium hypochlorite 0.55%) disinfectants are used daily and at discharge for all rooms occupied by adults. Pediatric rooms are disinfected daily using a quaternary ammonium compound; a sodium hypochlorite 0.55% disinfectant is used daily for contact precautions rooms and for all discharge cleaning. Most adult patient rooms outside of the intensive care units are double occupancy; all pediatric rooms are single occupancy. Patients with MDROs or CD receive care in a private room, are placed in a semiprivate room with the other bed blocked from occupancy, or are cohorted with another patient who harbors the same organism.

Pulsed xenon UVD (Xenex Corporation, Austin, TX) began in May 2011. In preparation for UVD use at our institution, we performed an assessment of the number and timing of contact precautions discharges and found the mean rate of contact precautions discharges was 0.87 per hour during peak discharge times of 2 p.m. to 6 p.m.[17] These data guided the decision of how many machines would be needed. Two machines were leased with the primary goal of disinfecting contact precautions rooms upon patient discharge or transfer. Training of Environmental Services staff began in May, and UVD was in routine use in July of 2011. In addition to use for contact precautions discharges, UVD was used after end of day cleaning in the operating rooms, weekly in the dialysis unit, and for all burn unit discharges. UVD could be requested for rooms of long-stay patients or for discharges in units with high prevalence of MDRO or CD. In rooms with more than 1 occupant, UVD was deferred until the room was no longer occupied.

The UVD procedure was the following: The bed management system (Teletracking, Pittsburgh, PA) used text pagers to notify Environmental Services staff of room cleaning needs. This system displays contact isolation status. The Environmental Services supervisor received the text page and was responsible for delivery of the UVD machine to the room and for the UVD. Housekeepers were instructed to start cleaning in the bathroom for contact precautions rooms. After cleaning, the UVD machine was started in the bathroom with the door closed, while the housekeeper cleaned the patient room. To reduce the opportunity for user error, UVD was used exclusively at the longer setting appropriate to inactivate CD spores; this included 6 minutes in the bathroom and 6 minutes each at 2 positions within the patient room. The time required was determined by the room size and protocol for machine placement. This was based on the manufacturer's measurement of the UV dose on high-touch surfaces and measured log reductions of microbes after UVD. The time for cleaning and UVD was recorded into the bed management system. The location of UVD use was entered in a logbook until October 2012. After that date, the UVD machines were upgraded, and location data were entered directly into the machines.

The use of UVD was monitored on a weekly basis by the Infection Prevention and Control, Environmental Services, and Performance Management departments. The number and reasons for use based on logbook entries and the machine location input were compared with the contact precautions discharges from the bed management system. When UVD was not performed, reasons were categorized as roommate, no machine available, urgent need for room, or unknown reason. When the reason was unknown, Environmental Services further investigated the cause.

During both the pre-UVD and the UVD periods, there were several initiatives to optimize environmental disinfection. Before UVD use, from July 2008 to December 2009, the hospital participated in the Greater New York Hospital Association CD initiative.[18] This initiative required use of checklists for environmental cleaning and engaging the Environmental Services Department in assuring discharge cleaning was adequate. Mercury UVD (Lumalier, Memphis, TN) was used on a limited basis in the medical intensive care and burn units from January 2009 to June 2010. A new Environmental Services contractor began in January of 2011. Throughout this study, cleaning was monitored using supplemental methods; Adenosine triphosphate (3M Cleantrace; 3M, Minneapolis, MN) was used in 2010, and UV fluorescent tracking markers (Dazo; Ecolab, St. Paul, MN) were used in the 2011 to 2013 period. In September 2012, during the UVD period, a new discharge cleaning checklist was adopted for use by Environmental Services supervisors.

Other health care-associated infection reduction initiatives included public reporting of CD to the New York State Department of Health starting in January 2010 and a change from CD cytotoxin A+B enzyme immunoassay (Meridian Bioscience, Cincinnati, OH) to real-time polymerase chain reaction (Cepheid, Sunnyvale, CA) in July 2010. In addition, a randomized double-blind trial of chlorhexidine bathing was conducted on a single unit, and weekly intensive cleaning of occupied rooms in high-risk units occurred throughout both the pre-UVD and UVD periods.

Definitions

MDRO cases were patients with organisms recovered from clinical cultures that include MRSA, VRE, or gram-negative bacteria susceptible to 2 or fewer classes of antibiotics. CD cases were defined as cases with a stool diagnostic test positive for CD. MDRO or CD cases were considered hospital acquired if there was no history of the organism and the onset of symptoms that led to recovery of the organism was present after 3 days of hospitalization and not incubating at admission or recovered within 48 hours after discharge. Incidence rates of MDROs and CD were defined as new hospital-acquired cases per 1,000 patient-days. Rate data were abstracted from Infection Prevention and Control databases without any links to individual patient information. This study was a quality improvement initiative that assessed summary data without individual patient identifiers.

Data analysis

Descriptive statistics were used to report the number of UVD cycles completed, the reasons for use, the percent of contact

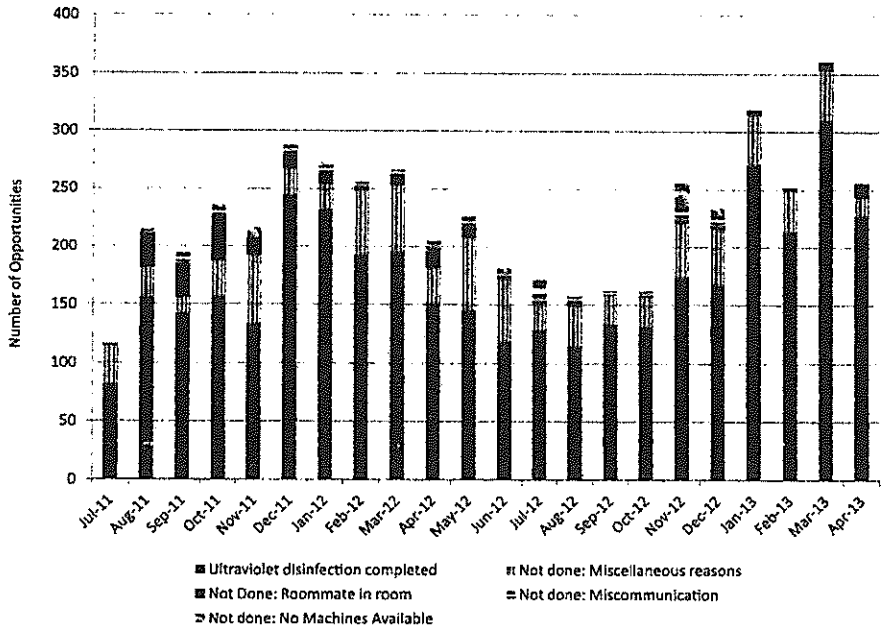

Fig 1. Ultraviolet disinfection use for contact precautions discharges and reasons for missed opportunities by month and year.

precautions discharge rooms that received UVD, the total time used, the average additional time needed for UVD, and the total utilization of the 2 UVD machines. Rate ratios with corresponding 95% confidence intervals and tests for trends in rates were estimated using Poisson regression. To assess the difference between the incidence rate before and during UVD use, piecewise regression was used.[19] The piecewise regression creates a combined model of the 2 time periods and compares the infection rates before and during UVD implementation. All data analyses were performed using Stata V.12.1 (StataCorp, College Station, TX).

RESULTS

UVD was performed 11,389 times from July 1, 2011, to April 30, 2013. Contact precautions discharges accounted for 3,833 (34%) uses, staff request for 3,695 (32%) uses, routine operating room and burn unit disinfection for 1,938 (17%) uses, and disinfection of bathrooms in occupied rooms accounted for 1,938 (17%) of uses.

Contact precautions rooms received UVD for 3,833 (76%) of discharges, with a range of 66% to 93% of discharges per month (Fig 1). The reasons for missed UVD upon discharge were miscellaneous 799 (67%) times, roommate was present 212 (18%) times, miscommunication with nursing 129 (11%) times, lack of availability of a machine 40 (3%) times, and because of urgent need for the room 9 (<1%) times.

UVD added an average of 51 minutes per discharge. This included approximately 31 minutes for arrival including setup of machine and setup of blackout curtains in areas that had open bays or glass windows and walls. UVD machines were in use for approximately 30% of the total time available. During the 22 months of UVD, changes were made to optimize utilization of the machines; these changes are summarized in Table 1.

The overall rates of hospital-acquired MDROs plus CD were stable for the 30 months before use of UVD ($P_{trend} = .89$) and for the 22 months during UVD ($P_{trend} = .28$) (Fig 2). However, the rate of hospital-acquired MDRO plus CD was significantly lower during the 22 months of UVD use compared with the 30-month period before UVD (2.14 cases per 1,000 patient-days vs 2.67 cases per 1,000 patient-days, respectively; rate ratio, 0.80; 95% confidence interval: 0.73-0.88, $P < .001$). The piecewise regression model showed a significant decrease in the infection rate during UVD use, $P < .001$. A subanalysis of the incidence rates of VRE, MRSA, CD, and resistant gram-negative bacteria demonstrated that each was significantly reduced during the UVD period (Table 2).

DISCUSSION

In this study, several implementation considerations were defined and monitored to optimize use of UVD. First, there was a method for automatically deploying the machines to contact precautions discharge rooms. In our hospital, the bed management system sends a text page that has the contact precautions message included. Second, a crucial factor was assuring availability of personnel to run the machines. Labor cost and availability must be considered in the budget and implementation plan for UVD. Our machines were in use 30% of the total available time in large part because of labor constraints, and labor constraints may have contributed to missing 24% of contact precautions discharge UVD opportunities. Staff is not primarily budgeted to run UVD; rather, this task is added onto the existing role of the staff or supervisor and may divert staff from other essential functions. Finally, our team discussed each contact precautions room missed on a weekly basis. This allowed us to uncover system flaws such as not assigning delivery of the UVD machines to a specific role at shift change, miscommunication in which Nursing told Environmental Services staff that UVD was not necessary, and unintended consequences such as deploying UVD to contact precautions rooms housing respiratory virus patients rather than only to those with MDROs and CD. It appears that UVD is feasible in our institution because it was cancelled less than 1% of the time because of immediate need for the room for patient care. Review of missed opportunities weekly has allowed us to improve our processes, although the need to evaluate utilization and missed opportunities is ongoing.

During the period of UVD, there was a 20% decrease in overall hospital-acquired MDRO plus CD. This statistically significant decrease in MDROs plus CD occurred in spite of missing 24% of

Table 1
Timeline of ultraviolet disinfection use changes and rationale

Month/year	Change	Rationale
8/2011	Environmental Services assigned the off-going supervisor to deliver the UVD machine to contact precautions rooms at change of shift.	To eliminate UVD misses at shift change.
9/2011	Contact precautions policy changed to require that patients who are eligible to have precautions stopped must be moved to a new room. Precautions are continued if they cannot be moved to a new room.	If precautions are discontinued and the patient remains in the room, the room will not be flagged for UVD at patient discharge.
4/2012	Discontinued use of UVD overnight in operating rooms.	A cleaning person was being diverted to run the UVD machine, resulting in a net loss of time dedicated to operating room cleaning.
5/2012	Routine use of UVD in bathrooms of occupied patient rooms added during non-peak discharge hours when staffing allowed.	Bathrooms are often highly contaminated, and it is feasible to use UVD in the bathroom with the door closed.
1/2013	Infection Prevention and Control is notified immediately if nursing told Environmental Services staff that UVD was not necessary.	Infection Prevention and Control can investigate communication breakdowns in real time and provide education to staff.
4/2013	Remove the isolation indicator that deploys UVD upon discharge from patients with respiratory viruses.	To maximize UVD availability for MDRO and CD room discharges.

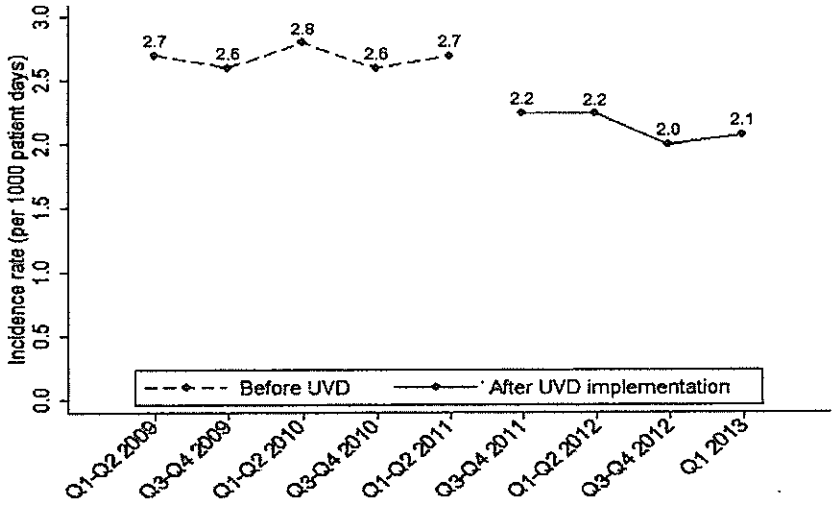

Fig 2. Incidence of hospital-acquired multiple drug resistant organisms plus *Clostridium difficile* from January 2009 until April 2013.

Table 2
Rates of hospital-acquired multiple-drug-resistant organisms and *Clostridium difficile* before and during ultraviolet disinfection

Organism	Before ultraviolet disinfection, 1/2009-6/2011		During ultraviolet disinfection, 7/2011-4/2013		Rate ratio, (95% confidence interval), *P* value
	No.	Rate per 1,000 pt-days	No.	Rate per 1,000 pt-days	
Total	1,320	2.67	749	2.14	0.80 (0.73-0.88) <.001
Vancomycin-resistant *Enterococcus*	443	0.90	257	0.73	0.82 (0.70-0.95) =.002
Clostridium difficile	390	0.79	228	0.65	0.83 (0.70-0.97) =.02
Methicillin-resistant *Staphylococcus aureus*	224	0.45	116	0.33	0.73 (0.58-0.92) =.007
Multiple-drug-resistant gram-negative bacteria	260	0.52	148	0.42	0.81 (0.66-0.98) =.04

Pt, patient.

opportunities for UVD of contact precautions rooms at discharge. Although there have been other studies of the effectiveness of UVD[8,11,12,15,20-22] for reducing vegetative bacteria and CD spores from environmental surfaces, this study is among only a small number of studies[14,16] evaluating rates of hospital-acquired pathogens in relation to the use of UVD.

The first clinical study in which UVD appeared to have a beneficial effect for reducing CD was reported by Sitzlar et al. They reported using UVD in a double occupancy room in a long-term care facility; 2 men acquired CD separately, but each had 2 recurrences of CD symptoms that were temporally associated. After treatment and UVD of the room, neither had further recurrences.[13] This same group of investigators studied environmental contamination with CD spores after sequential interventions of feedback about cleaning, UVD, and supervised cleaning.[8] They found that UVD decreased CD spore contamination in rooms but that cleaning was less rigorous during the UVD period. Supervised cleaning included the use of a 3-person dedicated daily disinfection team for high-touch surfaces in CD rooms and implementation of a process requiring that terminally cleaned CD rooms be "cleared" for the next patient by environmental services supervisors and/or infection control staff. In the period of supervised cleaning, CD spore contamination was eliminated by the cleaning, with no incremental benefit of UVD. In contrast, recent reports using a before and after design have associated UVD use with significant reduction in CD infection[14,16] and VRE acquisition.[14] The benefit of UVD versus standard

cleaning and supervised "research" level cleaning is an area for further research.

In our study, overall decreases in MDRO plus CD were led by a decrease in VRE, which is our most common hospital-acquired MDRO. VRE has a large environmental reservoir; we and others[15,23,24] have reported recovery of VRE from at least 23% to 25% of rooms housing infected or colonized patients. The importance of the environment as a potential source for VRE acquisition was demonstrated in a multivariate analysis in which VRE acquisition was significantly more likely if the prior occupant had VRE or if an environmental culture had been positive in the room.[1,2] Hayden et al[10] and Datta et al[9] found decreased VRE acquisition following intensive monitoring of and feedback about housekeeping procedures. Although there were many other simultaneous infection control interventions occurring at our hospital during the period from 2009 until 2013 that could have contributed to the reduction in VRE acquisition, the rates experienced during UVD are the lowest incidence rates of VRE at our institution for the past 10 years[25] and were sustained for 22 months.

The incidence rates of MRSA, CD, and MDR gram-negative organisms were also significantly lower during the UVD period. Although many simultaneous infection control initiatives could have contributed to these reductions, none appeared temporally associated with any reduction. For example, we had participated in CD reduction initiatives that included use of bleach-based disinfectants and cleaning checklists without any change in CD rates. Rates decreased during UVD use despite the transition to a more sensitive diagnostic test (polymerase chain reaction), which increased overall CD test positivity from 10% to 13%.

The limitations of this study include the before and after implementation of UVD design, which has inherent weaknesses, and the fact that this report is from a single institution. We did not evaluate antibiotic utilization, which can clearly affect acquisition rates of MDRO and CD. There were many simultaneous interventions occurring to reduce acquisition of MDROs and CD. However, the MDRO plus CD rates were stable for 30 months before initiation of UVD and only decreased during the first 6 months of the UVD period. These decreases were then sustained throughout the UVD period. Although the possibility of a cumulative effect of the multiple infection control interventions that were occurring during the pre-UVD period and continuing into the UVD period cannot be eliminated, our data suggest UVD use had an impact on these reductions.

Further study is needed to optimize the use of UVD and to further assess the effect of UVD use on acquisition rates of MDROs and CD. In addition, a cost-benefit analysis of UVD use that includes labor costs is also needed. Use of UVD as an adjunct to routine discharge cleaning of contact precautions rooms was feasible and temporally associated with a significant decrease in hospital-acquired MDRO plus CD in our institution.

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CAUSE NO. _____

XENEX DISINFECTION SERVICES LLC, *Plaintiff*	§	**IN THE DISTRICT COURT**
	§	**___ JUDICIAL DISTRICT**
v.	§	
SPECTRA254, LLC, *Defendant.*	§	**BEXAR COUNTY, TEXAS**

AFFIDAVIT OF PAUL FROUTAN

STATE OF TEXAS §
COUNTY OF BEXAR §

Before me, the undersigned notary, on this day, personally appeared Paul Froutan, a person whose identity is known to me. After I administered an oath to him, upon his oath, he said:

1. My name is Paul Froutan. I am over 21 years of age, am of sound mind and capable of making this Affidavit, and have never been convicted of a felony. The matters stated in this affidavit are true and correct and are within my personal knowledge.

2. I am the Chief Operations Officer for Xenex, and am responsible for establishing and optimizing operational processes, customer service, engineering, product development, supply chain, manufacturing and IT departments.

3. Save and except the factual assertions in paragraphs 8(B), 8(C), 11 and 12, which are separately verified by the affidavit of Mark Stibich, I verify that the factual assertions contained in the attached Application For Temporary Restraining Order And Temporary Injunction are true and correct.

Further affiant sayeth not.

PAUL FROUTAN

THE STATE OF TEXAS §
COUNTY OF BEXAR §

Sworn to and subscribed before me on by Paul Froutan on the 22 day of December 2014.

Notary Public Signature

LORI LEI GORRY
NOTARY PUBLIC STATE OF TEXAS
COMMISSION EXPIRES:
03-02-2016

{W0645817.1}

EXHIBIT 7

CAUSE NO. _____

XENEX DISINFECTION SERVICES LLC,	§	**IN THE DISTRICT COURT**
Plaintiff	§	
	§	
	§	**___ JUDICIAL DISTRICT**
v.	§	
	§	
	§	
SPECTRA254, LLC,	§	
Defendant.	§	**BEXAR COUNTY, TEXAS**

AFFIDAVIT OF MARK STIBICH

STATE OF TEXAS §
COUNTY OF BEXAR §

Before me, the undersigned notary, on this day, personally appeared Mark Stibich, a person whose identity is known to me. After I administered an oath to him, upon his oath, he said:

1. My name is Mark Stibich. I am over 21 years of age, am of sound mind and capable of making this Affidavit, and have never been convicted of a felony. The matters stated in this affidavit are true and correct and are within my personal knowledge.

2. I am the Chief Scientific Officer for Xenex. I hold a doctoral decree the Johns Hopkins University School of Public Health, a Masters in Health Science, also from Johns Hopkins, and a bachelor's degree from Yale University. I am a founder of Xenex and, as its Chief Science Officer, I oversee scientific research, product development, facility assessments, and protocol design.

3. I verify that the factual assertions contained paragraphs 8(B), 8(C), 11 and 12 in the attached Application For Temporary Restraining Order And Temporary Injunction are true and correct.

Further affiant sayeth not.

MARK STIBICH

THE STATE OF TEXAS §
COUNTY OF BEXAR §

Sworn to and subscribed before me on by Mark Stibich on the 22 day of December, 2014.

LORI LEI GORRY
NOTARY PUBLIC STATE OF TEXAS
COMMISSION EXPIRES:
03-02-2016

Notary Public Signature

{W0643816.1}

EXHIBIT 8

CIVIL CASE INFORMATION SHEET

CAUSE NUMBER *(FOR CLERK USE ONLY)*: _____ COURT *(FOR CLERK USE ONLY)*: _____

STYLED Xenex Disinfection Services LLC v. Spectra254, LLC
(e.g., John Smith v. All American Insurance Co; In re Mary Ann Jones; In the Matter of the Estate of George Jackson)

A civil case information sheet must be completed and submitted when an original petition or application is filed to initiate a new civil, family law, probate, or mental health case or when a post-judgment petition for modification or motion for enforcement is filed in a family law case. The information should be the best available at the time of filing.

1. Contact information for person completing case information sheet:

Name: J. Bruce Scrafford
Email: bscrafford@abaustin.com
Address: 100 Congress Ave., #1300
Telephone: (512) 435-2300
City/State/Zip: Austin, TX 78701
Fax: (512) 435-2360
Signature:
State Bar No: 17931100

Names of parties in case:

Plaintiff(s)/Petitioner(s): Xenex Disinfection Services LLC

Defendant(s)/Respondent(s): Specta245, LLC

[Attach additional page as necessary to list all parties]

Person or entity completing sheet is:

- [x] Attorney for Plaintiff/Petitioner
- [ ] *Pro Se* Plaintiff/Petitioner
- [ ] Title IV-D Agency
- [ ] Other: _____

Additional Parties in Child Support Case:

Custodial Parent: _____

Non-Custodial Parent: _____

Presumed Father: _____

2. Indicate case type, or identify the most important issue in the case *(select only 1)*:

Civil

Contract

Debt/Contract
- [ ] Consumer/DTPA
- [ ] Debt/Contract
- [ ] Fraud/Misrepresentation
- [ ] Other Debt/Contract: _____

Foreclosure
- [ ] Home Equity—Expedited
- [ ] Other Foreclosure
- [ ] Franchise
- [ ] Insurance
- [ ] Landlord/Tenant
- [ ] Non-Competition
- [ ] Partnership
- [ ] Other Contract: _____

Injury or Damage

- [ ] Assault/Battery
- [ ] Construction
- [ ] Defamation

Malpractice
- [ ] Accounting
- [ ] Legal
- [ ] Medical
- [ ] Other Professional Liability: _____
- [ ] Motor Vehicle Accident
- [ ] Premises

Product Liability
- [ ] Asbestos/Silica
- [ ] Other Product Liability
  List Product: _____
- [ ] Other Injury or Damage: _____

Real Property

- [ ] Eminent Domain/ Condemnation
- [ ] Partition
- [ ] Quiet Title
- [ ] Trespass to Try Title
- [ ] Other Property: _____

Related to Criminal Matters

- [ ] Expunction
- [ ] Judgment Nisi
- [ ] Non-Disclosure
- [ ] Seizure/Forfeiture
- [ ] Writ of Habeas Corpus—Pre-indictment
- [ ] Other: _____

Employment

- [ ] Discrimination
- [ ] Retaliation
- [ ] Termination
- [ ] Workers' Compensation
- [ ] Other Employment: _____

Other Civil

- [ ] Administrative Appeal
- [ ] Antitrust/Unfair Competition
- [ ] Code Violations
- [ ] Foreign Judgment
- [ ] Intellectual Property
- [ ] Lawyer Discipline
- [ ] Perpetuate Testimony
- [ ] Securities/Stock
- [ ] Tortious Interference
- [ ] Other: _____

Tax

- [ ] Tax Appraisal
- [ ] Tax Delinquency
- [ ] Other Tax

Family Law

Marriage Relationship

- [ ] Annulment
- [ ] Declare Marriage Void

Divorce
- [ ] With Children
- [ ] No Children

Post-judgment Actions (non-Title IV-D)

- [ ] Enforcement
- [ ] Modification—Custody
- [ ] Modification—Other

Title IV-D

- [ ] Enforcement/Modification
- [ ] Paternity
- [ ] Reciprocals (UIFSA)
- [ ] Support Order

Other Family Law

- [ ] Enforce Foreign Judgment
- [ ] Habeas Corpus
- [ ] Name Change
- [ ] Protective Order
- [ ] Removal of Disabilities of Minority
- [ ] Other: _____

Parent-Child Relationship

- [ ] Adoption/Adoption with Termination
- [ ] Child Protection
- [ ] Child Support
- [ ] Custody or Visitation
- [ ] Gestational Parenting
- [ ] Grandparent Access
- [ ] Parentage/Paternity
- [ ] Termination of Parental Rights
- [ ] Other Parent-Child: _____

Probate & Mental Health

Probate/Wills/Intestate Administration
- [ ] Dependent Administration
- [ ] Independent Administration
- [ ] Other Estate Proceedings
- [ ] Guardianship—Adult
- [ ] Guardianship—Minor
- [ ] Mental Health
- [ ] Other: _____

3. Indicate procedure or remedy, if applicable *(may select more than 1)*:

- [ ] Appeal from Municipal or Justice Court
- [ ] Arbitration-related
- [ ] Attachment
- [ ] Bill of Review
- [ ] Certiorari
- [ ] Class Action
- [ ] Declaratory Judgment
- [ ] Garnishment
- [ ] Interpleader
- [ ] License
- [ ] Mandamus
- [ ] Post-judgment
- [ ] Prejudgment Remedy
- [ ] Protective Order
- [ ] Receiver
- [ ] Sequestration
- [ ] Temporary Restraining Order/Injunction
- [ ] Turnover

4. Indicate damages sought *(do not select if it is a family law case)*:

- [ ] Less than $100,000, including damages of any kind, penalties, costs, expenses, pre-judgment interest, and attorney fees
- [ ] Less than $100,000 and non-monetary relief
- [ ] Over $100, 000 but not more than $200,000
- [x] Over $200,000 but not more than $1,000,000
- [ ] Over $1,000,000

CAUSE NO. 2014-CI-19749

XENEX DISINFECTION SERVICES LLC, *Plaintiff*	§	**IN THE DISTRICT COURT**
	§	37th **JUDICIAL DISTRICT**
v.	§	
SPECTRA254, LLC, *Defendant.*	§	**BEXAR COUNTY, TEXAS**

TEMPORARY RESTRAINING ORDER AND ORDER SETTING HEARING FOR PRELIMINARY INJUNCTION

On the 22nd day of December, 2014, the court heard Plaintiff's application for temporary restraining order.

1. The court, after examining the pleadings and affidavits, finds:

   a. Plaintiff will probably prevail against Defendant;

   b. Harm is imminent and irreparable to Plaintiff because Plaintiff and Defendant are competitors and Defendant is making false and misleading statements about the safety of Plaintiff's product in order to promote Defendant's product. Under these circumstances, harm is presumed pursuant to the Lanham Act.

   c. There is an inadequate remedy at law in the event an injunction is not issued because damages caused by false and misleading statements disparaging the reputation of a company and its product are difficult to quantify and not readily compensated by an award of money damages; and

   d. An ex parte order is necessary without notice to Defendant because Defendant has already made false and misleading statements about Plaintiff's product,

there is insufficient time to give notice to Defendant, hold a hearing, and issue a restraining order before additional harm occurs.

It is therefore ORDERED, ADJUDGED and DECREED as follows:

a. Defendant is enjoined to immediately cease publishing false and misleading statements about Plaintiff and its product, and in particular shall refrain from making additional statements to the effect that the Xenex Disinfection Device is unsafe because 1) the device was never tested for Safety UL 61010-1, 2) Xenex does not publish test data to demonstrate its device's effectiveness in killing pathogens and/or 3) Xenex never tested against Ebola; and

b. The clerk is ordered to issue notice to Defendant that the hearing on Plaintiff's application for temporary injunction is set for January 5, ~~2014~~ 2015, at 9:00 a.m./~~p.m.~~ in Presiding District Court, Bexar County Courthouse, 100 Dolorosa, Room 1.09, San Antonio, Texas 78205.

c. Bond is set for the issuance of the temporary restraining order in the amount of $ 500.00.

This Order shall remain in effect for 14 days from the date of signature unless extended pursuant to TEX. R. CIV. P. 680.

This Order is binding upon the parties to this action, their officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them who receive actual notice of the order by personal service or otherwise.

SIGNED this the 22nd day of December, 2014, at 1:50 ~~a.m.~~/p.m.

PRESIDING JUDGE

{W0643858.1}